# Zagallo Capsules Drug Use Investigation (202029)

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### Administrative details

EU PAS number EUPAS12703	
<b>Study ID</b> 48259	
DARWIN EU® study	
Study countries  Japan	

#### **Study description**

This investigation will be implemented to collect and evaluate the information on safety and effectiveness of Zagallo Capsules in male patients with androgenetic alopecia in daily clinical practice.

#### **Study status**

**Finalised** 

### Research institutions and networks

### **Institutions**

### GlaxoSmithKline (GSK)

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Multiple centres: 800 centres are involved in the

study

### Contact details

### Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

(Study contact)

Pharma.CDR@gsk.com

**Primary lead investigator** 

## GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

**Primary lead investigator** 

### Study timelines

#### Date when funding contract was signed

Actual: 24/09/2014

#### Study start date

Planned: 30/03/2016 Actual: 22/07/2016

#### **Date of final study report**

Planned: 30/09/2019 Actual: 13/12/2019

### Sources of funding

• Pharmaceutical company and other private sector

### More details on funding

GlaxoSmithKline

### Study protocol

gsk-202029-protocol-redact.pdf (177.07 KB)

### Regulatory

Was the study required by a regulatory body? Yes
Is the study required by a Risk Management Plan (RMP)?  Not applicable
Methodological aspects
Study type
Study type list
Study topic: Disease /health condition Human medicinal product
Study type: Non-interventional study
Scope of the study: Assessment of risk minimisation measure implementation or effectiveness Effectiveness study (incl. comparative) Safety study (incl. comparative)

### **Data collection methods:**

Primary data collection

### Main study objective:

This investigation is implemented to collect and evaluate the information on safety and effectiveness of Zagallo Capsules in male patients with androgenetic alopecia in daily clinical practice.

### Study Design

#### Non-interventional study design

Other

#### Non-interventional study design, other

Observational post-marketing surveillance

### Study drug and medical condition

#### Name of medicine, other

zagallo capsules

#### Medical condition to be studied

Androgenetic alopecia

### Population studied

#### Short description of the study population

Male patients aged 18 years or older diagnosed with androgenetic alopecia (AGA) receiving Zagallo for the first time for hair growth, hair restoration and prevention of hair loss under routine clinical practice from May 2016 to January 2019.

#### Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

#### Special population of interest

Hepatic impaired

**Immunocompromised** 

Other

Renal impaired

#### Special population of interest, other

Patients with androgenetic alopecia

#### **Estimated number of subjects**

4000

### Study design details

#### **Outcomes**

Information regarding the safety and efficacy of Zagallo Capsules under the actual post-marketing use conditions of the product.

#### Data analysis plan

Patient disposition ADR related itemsResponse rate based on the global assessment of effectivenessFactors considered influential on safety and effectiveness, odds ratio and 95% confidence interval thereof shall be calculated for the factors considered influential.

### **Documents**

#### **Study results**

gsk-202029-clinical-study-report-redact.pdf (975.57 KB)

### Data management

### **ENCePP Seal**

The use of the ENCePP Seal has been discontinued since February 2025.

The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

### Data sources

#### **Data sources (types)**

Other

#### Data sources (types), other

Prospective patient-based data collection

### Use of a Common Data Model (CDM)

#### **CDM** mapping

No

### Data quality specifications

### **Check stability**

**Check conformance** 

Unknown

### **Check logical consistency**

Unknown

### Data characterisation

#### **Data characterisation conducted**

No